EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC., Plaintiff,	)	CIVIL ACTION
v	)	NO. 20-753-LPS
ANNORA PHARMA PRIVATE LIMITED, Defendant.	)	NO. 21-196-LPS
BIONPHARMA INC., Intervenor.	)	

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Wilmington, Delaware
Friday, January 28, 2022
Telephonic Oral Argument

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BEFORE: HONORABLE LEONARD P. STARK, Judge

APPEARANCES:

MORRIS NICHOLS ARSHT & TUNNELL, LLP
BY: MEGAN E. DELLINGER, ESQ.
and
WENDY DEVINE, ESQ.
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BAYARD, P.A.
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BY: TODD S. WERNER, ESQ.
Counsel on behalf of Annora Pharma Private Limited

Now, one of the things that came up at our hearing with Your Honor in November was we told Your Honor that Azurity would have to launch the authorized generic, and that that would cause rippling irreparable harm. And I stand by that.

We did not have to launch the authorized generic because of the factual developments that happened shortly thereafter with Bionpharma. Here, we are poised to launch the authorized generic because we have notice that Annora wishes to launch at risk. And we won't have the sort of logistical delays that we had in doing so with Bionpharma. So that is a harm that was future at that time that remains future now that would apply here.

THE COURT: All right. On this accusation that your client is following a strategy to get later patents -- not later expiring, but later patents to cover your competitors' specific formulations. I understand from Ms. Hanson you all don't think that's relevant to her issues, but likely the step on the merits.

Are those contentions relevant to the equitable issues of irreparable harm and balance of harms and public interest?

MS. DEVINE: No, Your Honor, they're not.

When Annora filed their ANDA, they were aware that Azurity had some patents, that Azurity had multiple

the merits side of the equation. We heard, I just heard that any phosphate buffer is the same. Their expert didn't say that in his declaration, so I'm not sure what the evidence is on that. We haven't had a chance to address it.

And with respect to Dr. Buckton's statements, and the suggestion that those are limited to the prior art and don't take into account the teachings of the specification, I'm not sure what teachings in the specification need to be taken into account. There are none when it comes to any phosphate buffers, other than the generic reference, which was the same type of reference in the prior art already in the '747 patent. That those recipients could be used in an enalapril formulation. So I just -- I think it's irrelevant that it was focused on prior art in view of the complete paucity of disclosure and guidance set forth in the specification for the asserted patents.

THE COURT: Okay, thank you.

Thank you to all three of you for the argument.

I came into this argument, you know, well prepared and hopeful that I could make a decision quickly. And happily I find that I am able to make that decision and I'm going to give you that decision in just a moment.

I do want to preface it by saying the reason I came in with that hope and prepared an expectation of least

having that goal, and why I'm going forward is these are, I think, somewhat exigent circumstances.

We have a defendant who is on the cusp of being able lawfully to launch at risk and appears fully intending to do so.

While we do have a trial date later this year, I think about six months from now, there's, you know, always some degree of uncertainty with trial dates, and I say there's some uncertainty here in that regard. And further, even in the best of circumstances take typically some months to get an opinion out, as counsel know, in this type of circumstance.

So while I'm sure I could do a better job of articulating my reasoning if I take some time to write an opinion, I think under the circumstances I should do my best to give you my decision now.

I also am confident that the outcome would not change if I take that time; although probably the reasoning -- at least the clarity of the reasoning would, but I'll do my best today.

And further, I'm only going to address the bare minimum of issues that I need to address in order to explain the outcome here.

So with all that, the issue is the plaintiff Azurity's motion for a preliminary injunction. And for the

reasons I will endeavor to outline, I have decided to deny that motion. I'm denying the preliminary injunction.

As we all know, the motion relates to the two patents that remain in this case, the '868 and the '476. For purposes of the motion, Azurity focuses on a subset of six asserted claims, claims 11 and 12 of the '868 patent and claims 9, 10, 12 and 13 of the '476 patent.

I'm not going to address with any great specificity any differences among the claims within each of the patents because my analysis doesn't really turn on that.

As noted, and clear in the record, Annora does have tentative approval and appears likely eligible for final approval for its drug product in just a couple of weeks and trial is currently set, as I indicated, for July of this year.

The factors that Azurity must establish to obtain the extraordinary relief of a preliminary injunction, an injunction that would keep the defendant off the market, even before the merits of the parties' dispute have been fully assessed and that legal framework is well established and not disputed before the parties.

I'll just put on the record, Azurity quotes for the standard the Winter vs. NRDC decision of the Supreme Court in 2008, 555 U.S., a quote on Page 20. "A plaintiff seeking a preliminary injunction must establish that he is

likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities chips in his favor and that an injunction is in the public interest."

As I will explain, I find that Azurity has not met its burden on either of the first factors, so I must deny Azurity's motion. I will not be addressing the third and fourth factors.

Let me turn now to the first factor: The likelihood of success on the merits. First, Azurity is required to show, since this is a patent infringement dispute, a likelihood of success in proving infringement of one or more of the six claims on which the motion is based. This is not disputed, for purposes of the motion, and so the plaintiff has met its burden on that aspect of the likelihood of success showing.

But the issue comes up with respect to validity. To obtain a preliminary injunction, Azurity must show that Annora is unlikely to prove that the patent claims are invalid. The patents are all presumed to be valid. To overcome that presumption of patent validity and defeat the preliminary injunction motion, Annora must identify persuasive evidence of invalidity. And for that framework, part of which I have quoted, I would cite to the Federal Circuit decision of Purdue Pharma, LP vs. Boehringer

Ingelheim GmhB 237 F.3d, specifically at page 1365, again Federal Circuit in 2001.

And I conclude that Annora has presented persuasive evidence of invalidity with respect to each of the claims on which the PI motion is based. And that's because of written description and lack of enablement.

Let me talk about written description first. The written description requirement requires a patent application to convey to a person of ordinary skill in the art with reasonable clarity that the applicant was in possession of the invention as of the filing date. That standard is well settled. I'm citing now the NovaZymes vs. Dupont Nutrition decision of the Federal Circuit in 2013, 723, F.3d at 1344.

The written description test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. And we know the claimed invention need not be recited in haec verba. Those parts of the standard, I don't think are new, but they are set out newly in the Novartis vs. Accord decision 2022 Westlaw 1679 at star 4 from January 3rd of this year from the Federal Circuit.

The written description requirement cannot, however, be satisfied by data disclosed after the filing date, for that I cite Ariad vs. Eli Lilly 598 F.3d at 1355,

56 through Federal Circuit 2010.

Additionally, in undertaking the written description analysis, it is not proper to use hindsight; that is, the Court cannot start with the claims and then look back into the specification for individual elements.

The defendant cites the In re Ruschig decision of the C.C.P.A. in 1967, 379 F.2d at 995 for that proposition, and I think that that proposition does apply here.

I think it's clear from the record that small changes in this -- in embodiments in this art can make material differences. And so, I think that principle of law is applicable here.

There is no requirement that a patent disclose either examples or an actual reduction to practice. We know that from at least the Alcon vs. Barr decision 745 F.3d at 1190, Federal Circuit at 2019. However, as is uncontested, the absence of such material in the patent is a pertinent consideration as to whether a person of ordinary skill in the art would understand the patent applicant to have been in possession of the invention as of the filing date.

In my view that principle applies here and helps the defendant meet its burden on the written description defense, especially with respect to the '476 patent.

Annora argues, generally, that Azurity employs a

strategy of seeking patents covering competitor formulations not disclosed in specification, and that that is what it has done with the patents at issue here. It explained, for example, that the claims -- the claims in the '476 patent that are directed to using a citric and phosphate buffer system were first submitted in May of 2020, just a month after Annora disclosed its formulation to Azurity.

Annora also cites to events that occurred with respect to Bionpharma. And I would say there is some evidence in the record to support Annora's allegations about the timing with which Azurity seeks claims or has sought claims in this family of patents.

And I've considered that evidence, but I have not considered it for purposes of the invalidity argument. Though the defendant contends that it's indicative, I suppose, of a fact pattern that might lead one to think that these patents are invalid, for instance for lack of written description, I'm not -- I'm not persuaded by that argument.

I do think the issue goes more to the equitable consideration the Court always has to have in mind when confronted with a request for the extraordinary equitable relief of a preliminary injunction. But I have not considered the evidence for purposes of invalidity.

So let me turn to what I have considered on invalidity. I'll start on the '476 patent. And I'm still

talking about the written description defense.

The '476 patent claims that buffer comprising two specific agents, citric acid and disodium hydrogenphosphate. Yet the specification only contains a single isolated reference to disodium hydrogenphosphate in an exemplary, nonlimiting list of nearly 40 buffer agents. That reference is in column 13.

I understand the argument that we heard at least today that there's really a second reference to disodium hydrogenphosphate elsewhere in column 13. Even if I credit that, we have at best two isolated references and the combination, importantly, is not disclosed; not disclosed as preferred, not something that a person of skill in the art would understand to have been disclosed or possessed by the applicant at the time of the invention.

And even on the very limited record I have on this point, the Wikipedia reference, for example, it seems that a person with skill in the art would understand the purported second reference that plaintiff now identifies, for instance, on their slide five in column 13, is broad enough that it would encompass other phosphates as well.

Annora says, and I agree, at best these are faint blade marks in the specification to try to guide a person of skill in the art through the forest through the claimed invention. That's at best from plaintiff's

prospective.

The specification never discloses the use of disodium hydrogenphosphate with a second buffer agent; and, most importantly, does not disclose its use with or in a combination with citric acid. Instead, the specification focuses on a different buffer combination, citric acid and sodium citrate. Given the differences between citrate and phosphate, swapping a citrate buffer for a phosphate buffer could impact the performance of the buffers and formulation.

As Azurity itself told the FDA, and for that, and that's throughout the record, but I'll cite in particular D.I. 85 at 6 to 7, which cites D.I. 86-35 at 5853.

The specification, however, provides no guidance on these differences. So in the Court's view, a person of skill in the art would not have understood the inventors to have been in possession of the claimed buffer system.

Azurity replies that Annora's expert, Dr. Dash, admitted that the claimed buffer system is described in the specification. But when you look at his citation or the citations to his declaration, what you see is just his explanation that the specification refers to disodium hydrogenphosphate just once in the exemplary, nonlimiting list of nearly 40 buffer agents. That's not very persuasive evidence for the plaintiff.

Azurity also points to Dr. Dash's statement that the claimed buffer system is commonly known in the art and even has a colloquial name the "nickel vein" buffer. And the specification discloses a preferred embodiment with a sodium phosphate buffer, which Azurity alleges a POSA would understand to include disodium hydrogenphosphate.

So it's not -- I'm not suggesting there's nothing on the plaintiff's side of the ledger here, but there's not enough for them to prevail on this motion.

For reasons, in addition to all the ones I have already said, Annora points out that other aspects of the formulations claimed in the '476 patent are not described in the specification. For example, the specification never discloses the claimed citrate phosphate buffer at the claims concentration of about 5 nM to about 20 nM. But a person of skill in the art would know that the concentrations of the agent must be separately assessed.

I agree with Annora on this point that it's really only through hindsight that a person of skill in the art would be able to identify anything resembling this combination. The specification also does not disclose the claimed combination of the citrate phosphate buffer with the claimed sodium benzoate preservative as sucralose sweetener. Instead, the specification discloses over 26,000 different potential combinations of buffer agent preservative and

sweetener and provides no way for a person of skill in the art to divine the claims combination of these elements.

While the claims require a stability for 12 to 24 months, the specification lacks evidence of such stability for any single formulation covered by the plaintiffs.

So for at least all of these reasons, I agree with Annora that there is at least persuasive evidence that the '476 patent is invalid for lack of adequate written description.

I agree with Annora that considering the claims recitation of a specific buffer comprising two specific agents, the specification's general description a stable oral liquid formulation of enalapril, along with disclosure of a variety of buffers, preservatives and sweeteners without any working examples of the claimed formulation is insufficient evidence that the inventors possessed the claimed formulation; or at least, at very minimum, there's persuasive evidence that that's how a person who in skill of the art looking at this patent would view it.

So, none of the claims on which the patent -- excuse me, none of the claims of the '476 patent that are asserted as a basis for the preliminary injunction, with respect to none of those has the plaintiff met its burden to show a likelihood of success on the merits due to the

persuasive evidence, at minimum persuasive evidence of lack of adequate written description.

Turning to the '868 patent. I'm not addressing written description, because I find their persuasive evidence as to lack of enablement with respect to those claims, that is the claim of the '868. And let me turn to that now.

Enablement requires that the specification teach a person in the skill of the art how to make and use the full scope of the claimed invention without undue experimentation. The Court should consider the breath of the claims in relation to the amount of direction or guidance presented and the presence or absence of working example, among other things. And that legal standard is not a dispute. I would cite, in particular, to the ALZA vs. Andrix Pharmaceuticals decision of the Federal Circuit in 2010, 603 F.3d at page 90, of course In re Wands 858 F2.d at 737 as a decision from the Federal Circuit in 1988.

So focusing on the '868 patent, Annora argues that the claims cover any imageable buffer and permit the pH to be as low as zero and as high as 4.5. Relying on the specifications' nonlimiting examples of buffers -- and assuming they can be used as a combination, as Azurity asserts -- the patent contemplates at least 1400 buffer systems. Yet, the specification describes only a single

formulation using a single citric acid sodium citrate buffer at a narrow range of concentration.

In response to all of this, Azurity says that the specification through examples informs a person of skill in the art of the appropriate narrower pH range, which, in turn, informs the buffer selection; and, therefore, enables the claims to achieve the claims stability.

Azurity further contends that a person of skill in the art would be able to choose an appropriate buffer from a desired pH based on their knowledge and teachings from the specification. It follows, in Azurity's view, that undue experimentation is not necessary.

There's expert support in the record on both sides of these issues. Annora's Dr. Dash argues that the claims bear little resemblance to the limited guidance in the specification. While Azurity's Dr. Buckton then states that Example E in the specification provides real life data disclosing stability of an embodiment of '868 patent claims.

Having reviewed the evidence, I find that Annora has presented at least persuasive evidence that the '868 patent is invalid for lack of enablement.

I should point out with both the written description discussion and now the enablement discussion, I may have, in my haste to try to explain my ruling, said things that might suggest that I'm already finding by clear

and convincing evidence that these claims are invalid. I'm not.

All I am holding is that there's at least persuasive evidence of invalidity on the grounds that I have identified. And any language I may have used that seems broader than that is unnecessary. I do think that these may well be very strong defenses, but I don't have to make a conclusion on that, and I'm not making a conclusion on that.

Turning back, just briefly, to enablement. There's always an opinion from the defendant's expert that at least some number of inoperable embodiments are captured in the broad claims of the '868 patent and that, for this reason as well, undue experimentation would be necessary in order for the person of skill in the art to understand the full scope of what is actually enabled and claimed.

This is additional persuasive evidence that is sufficient to support my finding that the plaintiff has not met its burden to show a likelihood of success on the merits with respect to the claims of the '868 patents on which the motion is based.

So for all of those reasons, Azurity has failed to demonstrate a likelihood of success on the merits.

Let me turn, more briefly, to irreparable harm. In my view, Azurity has also failed to show irreparable harm, if -- as I am doing, I'm denying its motion for

preliminary injunction.

Azurity identifies a number of types of harms that might under other circumstances support a finding of irreparable harm. The parties here are direct competitors. This is a small -- or Azurity is a small specialty drug manufacturer. And Epaned, the product at issue in this litigation, is its flagship product and the defendant -- and the product is likely going to be substituted for Epaned.

As of today, there's market exclusivity. We heard, you know, late-breaking information that perhaps that will change, independent of my decision, as a result of the New York litigation between Bionpharma and CoreRx, its supplier. But as of today, it is true that Epaned is the only product in a ready-to-use liquid enalapril market.

The plaintiff has evidence that it will be harmed from the introduction into the market of a lower priced generic competitor. Annora's generic is obviously unauthorized and would, almost certainly, if introduced exert a downward pressure on the price of Epaned. And Azurity has said that it intends to launch its own authorized generic, which will also exert downward pressure.

I should be clear, Azurity has said if this motion is denied and if Annora does in fact intend to launch, then Azurity intends to launch its authorized generic. And even if ultimately further litigation were to

remove Annora's competitors product from the market, it would be difficult, I recognize, for the Epaned market price to go back to the higher price it's currently at. And that's true whether or not Azurity launches its authorized generic, but certainly all the more true, that is all the more difficult, if Azurity launches its authorized generic.

Azurity argues that it's going to have to scale back its education efforts related to its products and lose sales of its other products if it can't get its foot in the door as easily with its Epaned product. And also talks of -- and there's evidence for all those things, I recognize, loss of research and development opportunities, the possibility of employee layoffs, potential harm to the plaintiff's reputation and, perhaps, loss of access to funding.

All these things there's support for in the record, they all, I think, are harm, but the plaintiff has failed to persuade me on this record that any of those, individually or in combination, under the circumstances here constitute harm that would be irreparable.

One reason for Azurity's failure is the evidence with respect to what occurred in connection with Bionpharma's launch of it generic version of Epaned. The record appears to show that Azurity was not irreparably harmed by that launch and has fully recovered from it. That

is despite me, as the presiding judge in the Bionpharma case, having heard that essentially all the harms forecast now in this case, with respect to the pending motion here, would occur and would be irreparable were I to deny the preliminary injunction to stop Bionpharma's launch. I then denied that motion, Bionpharma launched and here we are months later, and I do not believe that Azurity has been irreparably harmed.

Now, two things: One, the record of all of that is fair for me to consider, much of it is in the record in this case. But beyond that, no one has argued I can't consider the Bionpharma situation. And I could take judicial notice of it as well.

But, second, I do want to emphasize, I recognize the circumstances are quite different here than in Bionpharma. I presume that Annora does not have the same supplier that Bionpharma did. And I'm sure it's unlikely that the parent or holder of some amount of equity of Azurity is going to go out and acquire or acquire some equity in whoever Annora retains as its supplier; and that fact pattern is unlikely to be repeated here.

But the important point to me is I don't know what will happen in the absence of granting the requested preliminary injunction, but I have real world experience with Azurity, real world experience with Azurity that it can

survive the launch of a generic, even when it told me that it would be irreparably harmed. At bottom, and most pertinently, Azurity just simply has not demonstrated that the harms it forecasts will befall it from a denial of its motion today will occur and will be irreparable.

In reaching that conclusion, I would also add that any alleged harms are likely quantifiable and monetarily compensable. This appears to have been true of the impact on the market from Bionpharma's launch of its unauthorized generic.

For example, Azurity's CEO and expert used data repositories to show the impact the Bionpharma generic had on Epaned's market share and price. And I have no reason to think that the same type of exercise cannot be undertaken after Annora's launch, if it turns out that Annora ultimately does not prevail on the merits and then is liable for damages to Azurity; I believe we will be able to calculate those damages with reasonable certainty.

The speculated loss of R&D opportunities, reduced sales of other products, layoffs and the other harms I listed before, in the context of this case I think Azurity can be compensated for these harms with a money judgment, probably a large money judgment. And, again, these are the same types of harms that were predicted to be both unavoidable and irreparable were Bionpharma to launch, but

that turned out not to be a correct prediction.

I'll add if it -- I have no reason to doubt that what I was told happened in the New York litigation this morning by counsel. It did in fact happen. If all of that means it's more likely that the status quo soon is going to be that there is a Bionpharma generic drug in this marketplace, that makes the plaintiff's failing to show irreparable harm for my denial of today's motion all the more glaring, but my decision is not based on that.

I imagine plaintiff is correct that there will be more litigation in that case, the New York case. And so I think that my decision is fully warranted, even on the assumption that Bionpharma won't be back in the market soon. But if Bionpharma will in fact be on the market soon, then it's even more difficult for the plaintiff to show irreparable harm from the introduction of a second unauthorized generic competitor than it would be to show for just one. And, so, that would only strengthen the basis of my decision.

Bottom line is Azurity has not met its burden to show that it will suffer irreparable harm in the absence of granting extraordinary relief of a preliminary injunction.

I'm not addressing balance of harms or the public interest, it's not necessary. The plaintiff has failed to met its burden on the first two required elements

of a preliminary injunction.

Also, I should just note, it's obvious from the record, I did not address the obviousness defense. Even if the plaintiff is right that the defendant did not come up with persuasive evidence of obviousness, that did not alter the outcome here given my findings on the other defendants.

So, I've said a lot. I don't want any more argument, but you may well have questions. And if so, I'll try my best to answer them.

First, either Ms. Devine or Ms. Hanson?

MS. DEVINE: Thank you, Your Honor. This is Wendy Devine for Azurity.

I am going to discuss this with my client and there is a possibility that we're going to want to appeal this order. And that we will want to seek some sort of temporary restraint to allow us to seek an emergent appeal.

If we do want that, how would Your Honor like us to approach the Court to discuss that?

THE COURT: Sure. I appreciate all of that.

As I'm sure you understand, first you should approach the defendant, and I did start that conversation with Mr. Werner. And I would be hopeful that they would be receptive to any reasonable request you might have.

I don't think any of us want to burden the Federal Circuit with an appeal that has to go any more